

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Status of the Claims

Claims 1-16, 18, 25-26, 45-46, 62-63, 68, and 82-99 were cancelled previously. Claims 22, 23, 39, 44, 60 and 61 have been amended with exemplary support in the specification, for example, at page 19, paragraph [0057]; and at page 20, paragraphs [0058] and [0059]. Claims 33, 54 and 76 have been amended to delete the term “derivative.” Claims 34, 36, 55, 57 and 79 have been amended to correct a typographical error.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, Claims 17, 19, 21, 23-24, 27-44, 47-61, 64-67 and 69-81 will be pending.

II. Statement of the Substance of Interview

Applicants thank Examiner Konata George and Examiner Mina Haganathian for the courtesies extended during an interview with Applicants’ representative, Christian Bauer, on April 16, 2008. The Examiners’ position was that U.S. Patent Publication No. 2002/0065256 to Karlsson et al. teaches a sterile, small particle, glucocorticosteriod dispersion. During the interview, Applicants’ representative pointed out that the claims require sterilization of the fluticasone by filtration, and in contrast, Karlsson filters only the aqueous components, and then aseptically combines it with the powdered steroid. *See*, for example, paragraphs [0044] and [0057]. The Examiners’ position was that Applicant’s element: “sterilized by filtration through a 0.2 µm filter” was a method step in a composition claim, and carries no patentable weight,

III. Claim Objections

Claims 36, 57 and 79 are objected to for containing typographical errors. The claims have been amended to remove the unnecessary comma after “and,” thereby obviating the basis for the objection.

IV. Rejection of Claims under 35 U.S.C. § 112, second paragraph

Claims 33, 54 and 76 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Applicants respectfully traverse the rejection.

Claims 33, 54 and 76 have been amended to delete the term “derivative.” Accordingly, Applicants respectfully request withdrawal of the rejection.

V. Rejection of Claims under 35 U.S.C. § 103 (a)

Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are rejected under 35 U.S.C. § 103(a) for alleged obviousness over U.S. Patent Publication No. 2002/0065256 to Karlsson et al. (“Karlsson”). Applicants respectfully traverse the rejection.

A. Applicant’s Method Claims

Claims 39-44, 47-61, 64-67 and 69-81 are method claims, which expressly recite that the entirety of the dispersion (including the fluticasone particles) passes through a 0.2µm filter to be sterilized. As noted above, Karlsson filters only the aqueous components, and then aseptically combines them with the powdered steroid. *See*, for example, paragraphs [0044] and [0057]. Karlsson does not teach or fairly suggest that its steroid is of a size that can pass through a 0.2µm filter. The rejection with respect to claims 39-44, 47-61, 64-67 and 69-81 is respectfully requested to be withdrawn.

B. Applicant's Composition Claims

Claims 17, 19-24, 27-43 are composition claims.

In response to the Examiner's view that the element "sterilized by filtration through a 0.2 μ m filter" or iteration thereof found in the independent claims 17, 22 and 23 is not given any patentable weight, the Applicant refers to the 15 October 2007 Restriction Requirement. The Restriction Requirement grouped claims 17 and 19-81 into Group II (subclass 424) as drawn to sterile filterable fluticasone. Group II was alleged by the Examiner to be independent and distinct from Group I, claims 1-16 (now cancelled) (subclass 489), which claims were directed to compositions that did not need to be prepared by sterile filtration. See top of page 3 of the Restriction Requirement.

As a result of the Restriction Requirement, Applicant elected to prosecute the claims of Group II.

By failing to give the claim element: "sterilized by filtration through a 0.2 μ m filter" patentable weight, the Examiner has taken a position that is inconsistent with the Examiner's previously issued Restriction Requirement. Any attempt by Applicant to continue prosecution of these claims would thus not be consonant with the Restriction Requirement. Applicant therefore requests that patentable weight be given to the element "sterilized by filtration through a 0.2 μ m filter" or that a new Restriction Requirement be issued for clarity of the record.

When the claim element of "sterilized by filtration through a 0.2 μ m filter" is given patentable weight by the Examiner, these claims are patentable over Karlsson for the same reasons that are articulated above.

CONCLUSION

When all the words in Applicant's claims are given patentable weight, the present application is distinguishable for the art of record and is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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